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Although 150,000 total knee replacement surgeries are performed annually in North America, current designs of knee prostheses have mechanical problems that include a limited range of motion, abnormal gait patterns, patellofemoral joint dysfunction, implant loosening or subsidence, and excessive wear. These problems fall into three categories: failure to reproduce normal joint kinematics, which results in altered limb function; bone-implant interface failure; and material failure.

Modern computer technology can be used to design, prototype, and test new total knee implants. Our design team uses the full range of CAD-CAM to design and produce implant prototypes for mechanical and clinical testing. Closer approximation of natural knee kinematics and kinetics is essential for improved patient function and diminished implant loads.

Current total knee replacement designs are based on 19th Century theories that the knee moves about a variable axis of rotation. Recent research has shown, however, that knee motion occurs about two fixed, offset axes of rotation. These axes are not perpendicular to the long axes of the bones or to each other, and the axes do not intersect. Bearing surfaces of mechanisms that move about axes of rotation are surfaces of revolution of those axes which advanced CAD technology can produce. Solids with surfaces of revolution for the two axes of rotation for the knee have been made using an HP9000 workstation and Structural Ideas Master Series CAD software at ArthroMotion.

The implant's CAD model should closely replicate movements of the normal knee. The knee model will have a range of flexion-extension (FE) from –5 to 120 degrees. Movements include varus, valgus, internal and external rotation, as well as flexion and extension. The patellofemoral joint is aligned perpendicular to the FE axis and replicates the natural joint more closely than those of existing prostheses. The bearing surfaces will be more congruent than current designs and should generate lower stresses in the materials.

The CAD solid model is converted to a three-dimensional (3-D) finite element model, which can be evaluated with 3-D nonlinear finite element analysis (FEA) techniques. The process of developing a finite element simulation involves the material behavior of the individual components as well as the full, 3-D geometry of each. In order to describe the geometry of prosthetic components, we can import CAD files directly in the Initial Graphics Exchange Specification (IGES) format or we can create polygonal representations of surface shapes from other computational descriptions of the components. The volumes contained within these 3-D surface descriptions represent the solid models in the CAD system and must be converted into a form usable with the FEA tools in a process known as "meshing" the volumes. The resulting meshes consist of an organized series of hexahedral-shaped (or approximately cubic) building blocks. The building blocks of each mesh fill the entire volume described by the corresponding surface, and the surface of the final mesh closely approximates the original polygonal or IGES surface description of the prosthetic component.

Each block within the mesh has particular material properties, which could be the same or different throughout the prosthetic component. Each block is acted on by forces exerted by adjacent blocks, by other prosthetic components, or by external forces. As each block is acted upon by a force, the resulting stresses within the block are calculated by the finite element code. The volumetric meshing procedure (i.e., the 3-D nature of the finite element model) allows the model to be stressed within the components, rather than only at the surfaces. A more complete and accurate prediction of stress-related failure in the implant results.

Material properties for each component are specified in the finite element models. The materials used in orthopedic implants typically have nonlinear stress-strain relationships, although in some cases these can be approximated by linear models in certain regions of operation. Ultra-high molecular weight polyethylene, for example, exhibits nonlinear stress-strain behavior, including creep behavior. Nonetheless, based on data available in the literature, an elastic material model was deemed adequate for current simulation objectives, because simulated loading occurs primarily in the elastic and near elastic range, and creep behavior has not been adequately quantified for an accurate creep model to be developed. Certainly when phenomena such as stress relaxation in press-fit situations are to be modeled and experimental creep data become more widely available, a more sophisticated creep model will be used. Currently we are developing material models for bone, so the bone-implant interface may be modeled.

In addition to geometry and material behavior, boundary conditions such as physiological forces acting on the implant components must be included in the finite element model. Force magnitudes and vectors are taken from the literature and are used in static FEA of the implants. The NIKE3D code—a nonlinear, 3-D FEA tool developed at the Lawrence Livermore National Laboratory—is used to perform the analysis and evaluate implant designs. Presently, we have completed statically loaded, 3-D nonlinear FEA of several currently marketed prostheses. Simulations were performed using loading conditions representative of standing at different angles of knee flexoin/extension as well as different angles of varus/valgus, and implant stresses were evaluated in each position. Based on these analyses, design recommendations can then be made to change the articular surface geometry in an effort to minimize articular surface and sub-surface stresses.

In addition, quasi-static simulations can be used to calculate implant kinematics, which can be compared with those of normal joints. Design changes in the articular surface geometry will have a direct impact on implant kinematics and, therefore, potential implant function and failure. The next step in the design evaluation procedure is to complete fully dynamic simulations of the finite element model. Dynamic simulations can provide a much more extensive understanding of in vivo implant loading during normal activities. Static and dynamic computer simulations can both be used to evaluate implant articular geometry and the bone-implant interface. Design issues such as geometry and material choices, coupled with in vivo loading conditions, play a key role in interface failures that can only be predicted using computational models.

Eventually our CAD solids will be exported to a CAM facility to produce prototypes that can be tested mechanically and eventually produced for patients. The use of computer modeling tools reduces the time and increases the ability to evaluate prototype implant components with several new modalities.